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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,097	11/17/2005	Ernesto Arenas	0380-P02991US1	1994

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1601 MARKET STREET
SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER	
HAMA, JOANNE	

ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,097	ARENAS ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,14-16,18-24,26-29,31,32,40,46,47,52,54 and 56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-5,7,14-16,18-24,26-29,31,32,40,46,47,52,54 and 56.

This Application is a 371 of PCT/IB03/04598, filed September 24, 2003, and claims priority to U.S. provisional Applications 60/413,046, filed September 24, 2002 and 60/494,595, filed August 12, 2003 and foreign Application, 0222162.0 filed in the United Kingdom, September 24, 2002.

Applicant filed an amendment to the claims March 24, 2005. Claims 6, 8-13, 17, 25, 30, 33-39, 41-45, 48-51, 53, 55, 57-67 are cancelled. Claims 4, 5, 7, 14-46, 18-21, 26, 28, 29, 31, 40, 46, 47, 56 are amended.

Claims 1-5, 7, 14-16, 18-24, 26-29, 31, 32, 40, 46, 47, 52, 54, 56 are pending.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-5, 7, 14-16, 18-24, 26-29, 31, 32, 40, 46, 47 drawn to a method of inducing or promoting dopaminergic neuronal development.

Group 2, claim(s) 52, 54, 56, drawn to a method of obtaining a factor or factors which enhance proliferation, self-renewal, survival, and/or dopaminergic development, induction, differentiation, or maturation in a neural stem, progenitor, or precursor cell, or other stem or neural cell expression Nurr1 above basal levels.

The inventions listed as Groups 1-2 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Unity of invention between different catagories of inventions will only be found to exist if the specific combinations are present. These combinations include:

1) a product and special process of manufacture of said product,

2) a product and a process of use of said product,

3) a product, a special process of manufacture of said product, and a process of use of said product,

4) a process and an apparatus specially designed to carry out said process,

5) a product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said product, and methods of making multiple products as claimed in the instant application, see MPEP § 1850.

In addition to this, at the time of filing, the art teaches that several genes, including Wnt1 and Nurr1 have been identified that control differentiation of dopaminergic and serotonergic neurons in the midbrain and hindbrain (Lee et al., 2000, Nature Biotechnology, 18: 675-679, page 675, 2nd col., 2nd parag.).

Groups 1 and 2 have a relationship with each other as they are similarly drawn to inducing or promoting neuronal development of dopaminergic neurons. However, the Groups are distinct from each other because Group 2 is a method of identifying other factors that can be used to induce or promote the development of dopaminergic neurons, while Group 1 is a method of inducing or promoting development of

dopaminergic neurons. The two groups require different and distinct steps from each other.

The inventions are further restricted as follows.

Group 1 comprises distinctly named Nurr1 family members (claims 2, 3) and one must be elected. Each family member is distinct from each other because each comprises a different structure and different biological activity. The search and examination of each Nurr1 family member is burdensome because the searches are not coextensive. Additionally, should Applicant elect, "Nurr1" from the election of claims 2, 3, Group 1 is further restricted as Nurr1 can be administered as a nucleic acid or as a protein (claims 4, 5) and one must be elected. Nucleic acids and proteins are distinct from each other because each comprises a different structure and function. The search and examination of nucleic acids and proteins is burdensome because the searches are not coextensive. It is noted that should Applicant elect "expressing Nurr1 above basal levels by introducing Nurr1 protein into the cell" of claim 5, this will be read as a DNA construct that expresses Nurr1 protein. In addition to this, should Applicant elect Nurr1 nucleic acid (claim 4), the claims are further restricted as Nurr1 can be administered as DNA or RNA. DNA and RNA administered to the cell have different structure and different modes of operation and are thus restricted. The search and examination for DNA and RNA is burdensome because the searches are not coextensive.

Group 1 consists of distinctly compounds of retinoids, retinoid derivatives, an activator of the retinoid X receptor (RXR), a repressor of the retinoid acid receptor (RAR), 9-cis retinal, DHA, SR11237, or LG849 (claim 16) and one must be elected.

Each compound is distinct from the other as each comprises a distinct structure and distinct biological activity. The search and examination for each is burdensome because the searches are not coextensive.

Group 1 consists of distinctly named growth factors or combination of growth factors (claim 18) which may be administered to the cell and one or a specific combination of growth factors must be elected. Each growth factor and each combination of growth factors is distinct from each other because each produces a unique biological effect. The search and examination for each growth factor or combination of growth factors is burdensome because the searches are not coextensive.

Group 1 is drawn to a method that can be carried out in vivo and in vitro (claim 21) and one must be elected. The steps used to treat cells in vivo are different from those used in vitro. The search and examination of in vivo and in vitro conditions of cells is burdensome because the searches are not coextensive.

Group 1 comprises distinctly named cells that can be co-cultured with the neural stem cells (claims 20, 22-24, 26, 27) and one must be elected. Each cell is distinct from each other because each has a distinct structure and biological activity. The search and examination of each cell type is burdensome because the searches are not coextensive. It is noted that "host cell" transformed with a nucleic acid or "host cell" containing introduced Wnt protein are two distinct cell types (claim 22) as proteins and nucleic acids comprise distinct structure and function.

Group 1 comprises distinct methods of using the cells: method of treating a patient (claims 29, 31, 32, 40), method of treating a cell with a toxin and screening for agents that affect the ability of a dopaminerginc neuron to recover (claim 46), and a method of testing a dopaminergic neuron to tolerate a toxin when in the presence of an agent (claim 47) and one must be elected. Each method is distinct from each other as each comprises different method steps. The search and examination of each method is burdensome because the searches are not coextensive.

Group 2 comprises a host cell transformed with nucleic acid encoding Wnt or is a host cell that contains introduced Wnt protein (claim 56, lines 5-7) and one must be elected. Nucleic acids and proteins are distinct from each other because they have different structure and biological function. The search and examination for protein and nucleic acid is burdensome because the searches are not coextensive.

Group 2 comprises cells which are additionally co-cultured with the stem cell (glial cell or type 1 astrocyte, claim 56, lines 10-11) and one must be elected. The cell types are distinct from each other because each comprises a distinct structure and biological activity. The search and examination for each cell type is burdensome because the searches are not coextensive.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Claim 7 of Group 1 comprises distinctly named Wnt proteins and one must be elected. Each Wnt protein is distinct from each other as each comprises a different structure and function. The search and examination of each Wnt protein is burdensome because the searches are not coextensive.

Claim 19 of Group 1 comprises distinctly named antioxidant conditions and one must be elected. Each antioxidant condition is distinct from each other because each comprises a distinct structure. The search and examination of each condition is burdensome because the searches are not coextensive.

Should Applicant elect "type 1 astrocyte" from the restriction above of a cell that is co-cultured with the stem cell (claims 20, 22-24, 26, 27), one region from which the astrocyte was obtained (claims 26, 27) must be elected. The sites from which the astrocyte are obtained distinct from each other as each comprise a different structure and different biological activity. The search and examination of each site from which an astrocyte is obtained is burdensome as the searches are not coextensive.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic:

Claims 1-5, 7, 14-16, 18-24, 26-29, 31, 32, 40, 46, 47 of Group 1 are generic for Wnt protein.

Claims 1-5, 7, 14-16, 18-24, 26-29, 31, 32, 40, 46, 47 of Group 1 are generic for antioxidant conditions.

Claims 1-5, 7, 14-16, 18-24, 28, 29, 31, 32, 40, 46, 47 of Group 1 are generic for site from which the type 1 astrocyte is obtained.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the Wnt proteins are distinct from each other because each comprise a different structure and biological activity; the antioxidant conditions comprise different structures; and the sites from which the type 1 astrocytes are obtained are distinct as they yield different populations of astrocytes.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Joanne Hama
Art Unit 1632